

REMARKS

Claim Rejections

Claims 1, 3-16, 21, and 23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Nichols et al. (US 5,843,099) in view of Yoon '949 (US 5,542,949), Burbank et al. (6,635,065), Yoon '112 (US 5,728,112), Blocher et al. (US 6,520,960), and Geiges, Jr. (US 5,830,231). Claims 2, 15, and 17-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Nichols et al. in view of Yoon '949, Burbank et al., Yoon '112, Blocher et al., and Geiges, Jr., as applied to claim 1, and further in view of Yoon et al. '943 (US 5,704,943).

Drawings

It is noted that the Examiner previously accepted the drawings as originally filed with this application.

Claim Amendments

By this Amendment, Applicant has amended claims 1 and 23 of this application. It is believed that the amended claims specifically set forth each element of Applicant's invention in full compliance with 35 U.S.C. § 112, and define subject matter that is patentably distinguishable over the cited prior art, taken individually or in combination.

The Applicant respectfully submits that the structures of the present invention are quite different from the structures of the citations and not obvious to those skilled in this field.

1. Concerning the first citation to Nichols et al.:

With respect to claims 1, 6 and 23, the first citation to Nichols et al. discloses a ligature carrier/clamp 10 including an elongated body 12, a fixed handle 18, a movable handle 22, an operating rod 32 fitted in the elongated body 12, a clamp jaw and a slender jaw.

Clamp jaw 58 is mounted on a disc 46 and carries clamp fingers 60 and 62; a slender jaw is mounted on a disc 48. The slender jaw is in the form of perforated

needle 64. The end of the needle 64 has an eye 66, through which a suture can be threaded. The configuration of the clamp jaw with its fingers and the jaw with the needle is such that, in the open position, there is space therebetween and the needle point the clamp fingers. The space is sufficient to be able to engage over and clamp the desired tissues. The upwardly directed portion of the needle beyond the bend reaches beyond the fingers 60 and 62 in the closed position. The eye 66 is thus above the fingers of the jaw so that a suture therethrough can be engage. The suture threaded through the eye 66 can be secured on its prosimal end by wedging it under one of the suture wedges 68 or 70 (referring to col. 3, line 59 to col. 4 line 10).

The ligature carrier/clamp 10 has been previously loaded with one or more monofilament or braided sutures. In the usual case for the right sacrospinous colpopexy, the two loaded sutures are threaded through the eye 66 of the needle 64 from left to right. (col. 4, line 24 to line 29).

As the jaws are closed by moving the thumb loop, the tissue is first clamped between the needle tip and the fingers of the clamp jaw. The handle is squeezed to close the jaws, and this advances the needle tip through the tissue as the tissue is held by the fingers of the clamp jaw. (col. 4, line 39 to line 44).

Thus, the jaws 58, 64 of Nichols et al. have special structures which are different from the structures of the lower jaws 82 and upper jaws 84 of the present invention. The jaws 58, 64 of Nichols et al. serve to penetrate the tissue which is then sutured by a suture. The object of the jaws 58, 64 of Nichols et al. is also different from that of the lower jaws 82 and upper jaws 84 of the present invention.

The loop ligature 20 of the present invention is totally different from the suture of the first citation. The lower jaws and upper jaws of the present invention is looped with the loop ligature, while the suture of the first citation is threaded through the eye 66 of the needle 64 of the first citation. They are quite different in both structure and usage.

In the present invention, the lower jaws and upper jaws are looped with two loop ligatures positioned between the lower and upper jaws. After the tissue is cut off, the divided pedicles of the tissue are bound by the loop ligatures. This is not seen in the first citation.

2. Concerning the second citation to Yoon '949:

The blade 48 of the present invention is fixedly disposed at front end of the second link 45 which is directly manually operated, not via the handles.

In Yoon '949, pivoting of grip member 66 causes lever 192 to move cutter ring 196 distally which, in turn, moves outer cylinder 90 distally via spacer 220 and shoulder 118 causing the distal end of the outer cylinder to act as a collar and engage cams 120 and 122 to close the jaws to engage tissue as desired. Due to the spacer 220 being disposed between the cutter ring 196 and the shoulder 118, the cutter blade 56 is prevented from moving distally to a position where the blade could enter the jaws. Accordingly, tissue cannot be inadvertently cut by the blade since the sharp distal end 159 of the cutter blade remains within the outer cylinder 90. (col. 6, lines 13 to 25)

When it is desired to cut tissue after a clip has been applied, spacer 220 is rotated out of the position between cutter ring 196 and shoulder 118 such that, upon squeezing of the grip members 64 and 66, a clip will initially be applied to tissue since spring 204 is stronger than spring 202; and, thereafter, cutter ring 196 will be moved distally relative to shoulder 118 causing the distal end of the cutter blade to slide into the jaws along grooves 80 and 82 to cut tissue clipped and held by the jaws. If it is desired to selectively cut tissue without immediately following clipping with a cutting action, no clip is loaded into the jaws and the spacer 220 is moved from the engaged position such that the cutter blade can be moved distally by squeezing the grip members 64 and 66. (col. 6, line 62 to col. 7, line 8)

In Yoon '949, it is recited in col. 7, lines 54-57 that: *ju* The proximal end of the cutter blade 56' can be connected to a knob extending from housing 44 to allow movement of the cutter blade without squeezing the handle 57*iv*. Such recitation fails to clearly teach that the cutter blade 56' is directly operated by hand.

In Yoon '949, the cutter blade 56 is controlled by the grip member 66 and the lever 192 to displace, not directly operated by hand. This is different from the present invention.

In Yoon '949, many complicated mechanisms are used to control/operate the cutter blade 56. These mechanisms are quite different from the structure of the

second link of the present invention. As a whole, Yoon '949 has a very complicated structure which can be hardly applied to Nichols et al.

More importantly, the clamp jaw 58 and the slender jaw 64 of the first citation to Nichols et al. are destined to penetrate the tissue. According to the structures of the two jaws, it is impossible for a blade to extend therebetween for cutting the tissue. It is impossible for those skilled in this field to combine the first and second citations under the teaching of Yoon '949.

3. Concerning the third citation to Burbank et al.:

The two first tracking members 75 of the present invention are two elongated flexible members such as steel strings. The rear ends thereof are connected with the pull ring 70, while the front ends are for connecting with the loop ligature 20. When pulling the pull ring, via the first tracking members, the loop ligature is contracted. The first tracking members serve as media between the pull ring and the loop ligature for drivingly connecting the pull ring and the loop ligature.

In the third citation to Burbank et al., it is recited in col. 10, lines 14-23 that the extendable members 120, 122 serve to bracket a vessel 10. The object of the extendable members 120, 122 is different from that of the present invention. To those skilled in this field, the extendable members 120, 122 of the third citation fail to obviously implicate the first tracking members of the present invention.

In the third citation to Burbank et al., the first and second actuation rings 112, 114 are fixedly connected with the block 190, one ends of the extendable members 120, 122 are passed through the block 190. Two upstanding tabs 116, 118 through the slots 192, 194 are connected with the extendable members 120, 122 for driving the same to slide. The third citation further includes a suture advancing element 134 and a snaring element 136 respectively mounted in the extendable members 120, 122. Such structures of Burbank et al. are quite different from the pull ring and first tracking members of the present invention in both object and configuration.

4. Concerning the fourth citation to Yoon '112:

The fourth citation to Yoon '112 includes only an upper jaw 34 and a lower jaw 28, not two upper jaws and two lower jaws. Therefore, Yoon '112 has a structure different from that of the present invention.

In Yoon '112, the portion denoted 52 is a slotted opening formed in jaw 34, it is not the lower gap or upper gap of the present invention. The portion denoted 96 is a groove extension formed on the inner surface 40 of jaw 28, it is also not the lower gap or upper gap of the present invention.

The upper gap 841 of the present invention passes through the two upper jaws 84, while the lower gap 821 passes through the two lower jaws 82. Also, the upper and lower gaps communicate with the fissure 42 of the first link 40. Therefore, the blade 48 installed in the fissure can extend through the gaps and protrude from the front end of the forceps mouth 80.

In Yoon '112, the slotted opening 52 and the groove extension 96 are simply formed on the surfaces of the jaws 28, 34 and are unable to accommodate a blade and unable for the blade to extend therethrough. To those skilled in this field, the teaching of the fourth citation to Yoon '112 fails to implicate the structure of the present invention. Also, the fourth citation to Yoon '112 fails to anticipate the present invention in view of the first citation to Nichlos et al.

5. Concerning the fifth citation to Blocher et al.:

The two small blades 95 of the present invention are used to cut off the segments of the loop ligatures.

The fifth citation to Blocher et al. provides a BIPOLAR MEDICAL INSTRUMENT FOR CUTTING TISSUE, including: two working elements 14, 16 being configured as electrodes connectable to high frequency current. In the fifth citation, the portions denoted 56, 60 are a first projection and a second projection. The object of the projections 56, 60 is to achieve a concentration of the current density for cutting off tissue or a vessel.

The projections of Blocher et al. are different from the small blades of the present invention in both object and usage. To those skilled in this field, the teaching of the

fifth citation fails to anticipate the lower jaws with small blades of the present invention in view of the first citation.

6. Concerning the sixth citation Geiges, Jr.:

The press unit 50 of the present invention serves to drive the second and third tracking members 76, 78. The second tracking member 76 is first driven and then the third tracking member 78 is driven. The second tracking member serves to drive the segments of the loop ligatures 20, while the third tracking member serves to drive the pull member 105.

In the sixth citation to Geiges, Jr., working tips at the end of the cannula G, such as a clamp K, are closed by pressing against the trigger 23 with the index finger, and are opened by releasing pressure on the trigger. (col. 4, lines 5 to 8)

The trigger 23 is a modular sliding trigger. It is slidably received in the grip 21 and is not connected to the handle. The trigger 23 includes a spur 40 which extends into the rearward extension 24. Finger pressure on the trigger 23 causes corresponding rearward movement of the spur 40 in the rearward extension 24. An actuating pin 41 rises from the spur to register with the annular groove 38 in the transfer cylinder and thereby operably connect the trigger 23 to the tool at the distal end of the rod 37. Pressure on the trigger moves the rod 37 rearwardly. When rearward pressure is removed from the trigger 23, the adjustable tension spring 26 tends to return the rod to its forward or normal position. (col. 5, lines 17 to 29)

In Geiges, Jr., the spur 40 and the actuating pin 41 are parts of the trigger 23, not independent elements. This is different from the second and third tracking members of the present invention. The press unit 50, the second tracking member 76 and the third tracking member 78 of the present invention are all independent elements.

The second and third tracking members of the present invention are successively driven by the press unit. In contrast, the spur 40 and the actuating pin 41 of the sixth citation to Blocher et al. are simply extensions of the trigger 23.

Besides, in the sixth citation to Geiges, Jr., the trigger 23 (including the spur 40 and the actuating pin 41) drives the rod 37 for controlling opening/closing of the working tip K. In the present invention, the handles drive the first link 40 to control

opening/closing of the upper jaws 84. Therefore, the rod 37 of the sixth citation is more similar to the first link 40 of the present invention (but not the same). The rod 37 is pretty different from the second and third tracking members 76, 78 of the present invention in operation and object.

To those skilled in this field, the trigger 23 and the rod 37 of the sixth citation to Geiges, Jr. fails to implicate the second and third tracking members of the present invention. Also, the sixth citation fails to anticipate the present invention in view of the first citation.

7. Concerning the seventh citation to Yoon et al. '943:

The seventh citation to Yoon et al. '943 fails to disclose that the ligature loop 70 is converted from slippery knot into secure knot.

In the present invention, the loops 21 of the loop ligatures 20 are wound along the peripheries of the upper and lower jaws 82, 84. This is not disclosed in the seventh citation.

In the present invention, an end of the first segment being connected with front end of each first tracking member, an end of the second segment being connected with front end of the second tracking member, two ends of the pull member being respectively connected with the two segments of each loop ligature; the two segments of the loop ligature are driven by the pull member to move toward the small blades to be cut off by the small blades. This is also not disclosed in the seventh citation.

The upper and lower jaws of the present invention are different from the seventh citation. In the present invention, the bottom face of the rear end of each lower jaw is formed with a guide channel; the pull member being flexible, two ends of the pull member being respectively conducted through the guide channels and reversely upward folded through outer sides of the two lower jaws to respectively connect with the sutures of the two loop ligatures. This is also not disclosed in the seventh citation.

The structure of the jaws of the present invention is different from the seventh citation to Yoon et al. '943.

The seventh citation to Yoon et al. '943 fails to disclose the recess 821, steel plates 85, locating member 100 and insertion dent 825 disposed on the jaws of the present invention.

Therefore, the seventh citation fails to implicate the detailed structure claimed in claims 17 and 20 of this application.

Even if the teachings of Nichols et al., Yoon '949, Burbank et al., Yoon '112, Blocher et al., Geiges, Jr., and Yoon '943 were combined, as suggested by the Examiner, the resultant combination does not reasonably teach: each of the two upper jaws has a circumferential groove extending around a periphery thereof and communicating with the upper gap; the two lower jaws being fixedly disposed at the front end of the barrel; nor does the combination teach the upper jaws are movable between open and closed positions relative to the lower jaws and the lower jaws remain in a fixed position relative to the barrel.

It is a basic principle of U.S. patent law that it is improper to arbitrarily pick and choose prior art patents and combine selected portions of the selected patents on the basis of Applicant's disclosure to create a hypothetical combination which allegedly renders a claim obvious. The Supreme Court, in *KSR International Co. V. Teleflex Inc. et al.*, 550 U.S. 1, 82 USPQ2d at 1391 (2007), reaffirmed the framework of *Graham v. John Deere Co. of Kansas City* for determining obviousness under 35 U.S.C. 103. In that decision, the Supreme Court stated, at page 2:

In *Graham v. John Deere Co. of Kansas City*, 383 U. S. 1 (1966) , the Court set out a framework for applying the statutory language of §103, language itself based on the logic of the earlier decision in *Hotchkiss v. Greenwood*, 11 How. 248 (1851), and its progeny. See 383 U. S., at 15–17. The analysis is objective:

“Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such

secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *Id.*, at 17–18.

While the sequence of these questions might be reordered in any particular case, the factors continue to define the inquiry that controls. If a court, or patent examiner, conducts this analysis and concludes the claimed subject matter was obvious, the claim is invalid under §103.

The Supreme Court, further explained that:

Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) ("**[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness**"). *KSR* at 1396 (*Emphasis Added*).

Applicant submits that the above-presented arguments clearly indicate that the Examiner has failed to provide an "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness" for combining selected elements of Nichols et al. with selected elements of Yoon '949, Burbank et al., Yoon '112, Blocher et al., Geiges, Jr., and/or Yoon '943. *KSR* at 1396 (citing *In re Kahn* at 988). Clearly, such a combination is not an acceptable combination under 35 U.S.C. §103. The rejections of Applicant's claims as being rendered by the

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aforementioned combinations of references under 35 U.S.C. §103 are respectfully traversed.

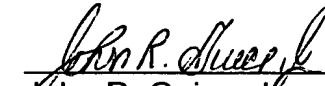
Summary

In view of the foregoing amendments and remarks, Applicant submits that this application is now in condition for allowance and such action is respectfully requested. Should any points remain in issue, which the Examiner feels could best be resolved by either a personal or a telephone interview, it is urged that Applicant's local attorney be contacted at the exchange listed below.

Respectfully submitted,

Date: April 30, 2008

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